REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

I. Amendments to the Specification and Claims

In the specification, the Title has been amended to better reflect the subject matter of the application. The specification has also been amended to include a cross-reference to related patent applications and to delete the recitation of hyperlinks and/or other forms of browser-executable code by inserting replacement paragraphs. The replacement paragraphs do not include new matter.

This amendment also adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

Claims 8, 10, 13, 15, 27, and 28 are requested to be cancelled, without prejudice or disclaimer of the subject matter. Applicants reserve the right to prosecute the subject matter of these claims in this or another application(s).

Claims 1-7, 9, 11, 16, 17, 19, and 22 are currently being amended to advance prosecution of this application. Specifically, claims 1 and 2 have been amended to recite an isolated polypeptide related to SEQ ID NO:1. Claim 3 has been amended to recite a polynucleotide that encodes a polypeptide related to SEQ ID NO:1. Claims 4 and 5 have been amended to recite specific SEQ ID NOs. Claim 6 has been amended to correct a typographical error. Claim 7 has been amended to recite an "isolated" cell and to correct a typographical error. Claim 9 has been amended to correct a typographical error. Claim 11 has been amended to recite an isolated polynucleotide related to SEQ ID NO:7. Claim 16 has been amended to correct a typographical error. Claim 17 has been amended to recite a polypeptide related to SEQ ID NO:1. Claims 19 and 22 have been amended to correct typographical errors.

Claims 57-61 are requested to be added. Claims 57-61 depend from claim 1, which is currently under consideration as part of elected Group I, "drawn to a polynucleotide, a polypeptide, and methods of use, only in so far as they relate to SEQ ID NO:1." As such, Applicants request that the Examiner consider the merits of claims 57-61.

Support for amended claims 1-7, 9, 11, 16, 17, 19, and 22 and new claims 57-61 is provided in the specification and claims as originally filed.

After amending the claims as set forth above, claims 1-7, 9, 11, 16, 17, 19, 22, 26, and 57-60 are now pending in this application.

Because the foregoing amendment does not introduce new matter, entry thereof by the Examiner is respectfully requested.

II. Objection to the Disclosure

The disclosure was objected to for including "an embedded hyperlink and/or other form of browser-executable code." The specification has been amended to delete any hyperlink and/or other form of browser-executable code. Withdrawal of this ground for objection is respectfully requested.

III. Objections to the Claims – Markush Groups

Claims 1-7, 9, 11, 13, 15-17, 19, 22, and 26-28 were objected to "as reciting an improper Markush Group...because they refer to six different amino acid sequences." The claims have been amended to refer to a single amino acid sequence (*i.e.*, SEQ ID NO:1), or a single polynucleotide sequence (*i.e.*, SEQ ID NO:7). Withdrawal of this ground for objection is respectfully requested.

IV. Objection to the Claims – Dependency

Claims 3-7, 13, 15, 19, 22 and 26-28 were objected to "as being of improper dependent form for failing to further limit the subject matter of a previous claim." In particular, the Examiner objected to claims 3 and 13. Claim 3 has been rewritten as an independent claim. Claim 13 has been cancelled. Withdrawal of this ground for objection is respectfully requested.

V. Rejection – 35 U.S.C. § 101, Lack of Utility

Claims 1-7, 9, 11, 13, 15-17, 19, 22, and 26-28 were rejected under 35 U.S.C. § 101 allegedly "because they are drawn to an invention with no apparent or disclosed specific and substantial credible utility." Applicants respectfully traverse the rejection for the following reasons.

The specification asserts that SEQ ID NO:1 is a "Cysteinyl leukotriene receptor." *See* U.S. 2004-0220092 at paragraph **[0339]**, TABLE 2. Further, the specification indicates that SEQ ID NO:1 includes "Signature Sequences, Domains and Motifs," which are characteristic of cysteinyl leukotriene receptors. *See id.* at paragraph **[0340]**, TABLE 3. U.S. provisional application no. 60/199,084, filed on April 20, 2000, to which the present application claims benefit, also asserts that SEQ ID NO:1 is a Cysteinyl leukotriene receptor. *See* U.S. appl. no. 60/199,084, at TABLE 2.

Subsequent to the filing date of the present application, others confirmed that SEQ ID NO:1 is a cysteinyl leukotriene receptor, referred to as "human cysteinyl leukotriene 2 receptor." *See, e.g.,* Heise *et al.*, *Characterization of the Human Cysteinyl Leukotriene 2 Receptor*, J. BIOL. CHEM. (September 2000), Vol. 275, No. 39, pp. 30531-30536, [hereinafter "Heise"], EXHIBIT 1. Heise indicates that cysteinyl leukotriene receptors mediate contractile and inflammatory actions of cysteinyl leukotrienes. Therefore, SEQ ID NO:1 has an asserted utility that is specific, substantial and credible. Withdrawal of this ground of rejection is respectfully requested.

VI. Rejection – 35 U.S.C. § 112, Lack of Utility

Claims 1-7, 9, 11, 13, 15-17, 19, 22, and 26-28 were rejected under 35 U.S.C. § 112 allegedly "as failing to adequately teach how to the use the instant invention for those reasons given above with regard to the rejection of these claims under 35 U.S.C. § 101." Applicants respectfully traverse the rejection for the reasons stated above with respect to the rejection under 35 U.S.C. § 101 for alleged lack of utility and request that the rejection be reconsidered and withdrawn.

VII. Rejection – 35 U.S.C. § 112, first paragraph, "Written Description"

Claims 1, 3, 6, 7, 9, 11, 13, 15, 16, 19, 22, 26, and 28 were rejected under 35 U.S.C. § 112, allegedly "as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." In particular, the Examiner asserted that the "instant specification does not contain an adequate written description [of] that genus of molecules encompassed by the limitations 'encoding' 'a naturally occurring polypeptide comprising an amino acid sequence at least 90% identical to' 'SEQ ID NO:1' or 'a naturally occurring polynucleotide comprising a polynucleotide sequence at least 90% identical to a polynucleotide sequence' of SEQ ID NO:9 [sic]." Applicants respectfully traverse the rejection for the following reasons.

First, claims 1, 3 and 11, from which all other pending claims depend, have been amended to recite "95% sequence identity." In addition, claims 1, 3, and 11 have been amended to recite a functional activity for the polypeptide (*i.e.*, "cysteinyl leukotriene receptor activity").

The specification asserts a function for the claimed sequences (*i.e.*, "cysteinyl leukotriene receptors"). The specification also discloses various structural and functional domains of SEQ ID NO.1 and SEQ ID NO:7. At Table 3, the specification indicates that SEQ ID NO:1 includes " potential phosphorylation sites"; a "potential glycosylation sites"; and "signature sequences, domains and motifs." *See* U.S. 2004-0220092, paragraph **[0340]**, TABLE 3. Assays for determining the function and measuring the activity of cysteinyl leukotriene receptors are known in the art. *See, e.g,* Heise, at EXPERIMENTAL PROCEDURES.

The U.S. PTO has provided guidelines for determining whether the written description requirement is satisfied where a claim recites a "Product by Function." *See* "Revised Interim Written Description Guidelines Training Materials," [hereinafter "Guidelines"], EXHIBIT 2, available at http://www.uspto.gov/web/menu/written.pdf. In particular, Example 14 of the Guidelines provides circumstances under which a claim to "[a] protein having SEQ ID NO:[#] and variants thereof that are ***at least 95% identical*** to SEQ ID NO:[#] and catalyze the reaction of A→B" is fully supported by a given specification. *See id.* at page 53 (emphasis added). As indicated in Example 14, a "[specification] meets the requirement of 35 U.S.C. 112, first paragraph as providing adequate written description for the claimed invention," where:

> The specification exemplifies a protein...that catalyzes [a] reaction....The isolated protein was sequenced and determined to have the sequence as set forth [by] SEQ ID NO:[#]. The specification also contemplates but does not exemplify variants of the protein wherein the variant can have any or all of the following: substitutions, deletions, insertions and additions. The specification indicates that procedures for making proteins with substitutions, deletions, insertions and additions is routine in the art and provides an assay for detecting the catalytic activity of the protein.

Under these circumstances, "[o]ne of skill in the art would conclude that applicant was in possession of the necessary common attributes possessed by the members of the genus" recited by the claim. *Id.*

Moreover, consistent with recent Federal Circuit ruling and M.P.E.P. guidelines, Applicants need not have provided explicit disclosure for each and every nucleic acid sequence that encodes a polypeptide of SEQ ID NO:1. Specifically, the Federal Circuit recently stated that "the complete amino acid sequence of a protein may put one in possession of the genus of DNA sequences encoding it...even if individual species within that genus might not have been described or rendered obvious." *See In re Wallach*, 378 F.3d 1330, 1333-34 (Fed. Cir. 2004) (citation omitted). Continuing, the Federal Circuit stated that "we see no reason to require a patent applicant to list every possible permutation of the nucleic acid sequences that can encode a particular protein for which the amino acid sequence is disclosed, given the fact that it is...a routine matter to convert back and forth between an amino acid sequence and the sequences of the nucleic acid molecules that can encode it." *See id.*

In addition, the M.P.E.P. states that "[d]escription of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces." *See* M.P.E.P. 2163.II.A.3(a)ii) (8th ed., rev. 2 2001). Continuing, the M.P.E.P. states that

> in the molecular biology arts, if an applicant disclosed an amino acid sequence, it would be unnecessary to provide an explicit disclosure of nucleic acid sequences that encoded the amino acid sequence. Since the genetic code is widely known, a disclosure of an amino acid sequence would provide sufficient information such that one would accept that an applicant was in possession of the full genus of nucleic acids encoding a given amino acid sequence, but not necessarily any particular species.

See id. (citation omitted).

As such, Applicants need not have provided explicit disclosure for each and every nucleic acid sequence that encodes a polypeptide of SEQ ID NO:1. Rather, because the specification discloses a polypeptide of SEQ ID NO:1, one skilled in the art would recognize that Applicants were in possession of the genus of DNA sequences encoding SEQ ID NO:1. For example, it is well known in the art that an amino acid may be encoded by more than one codon triplet. The genus of DNA sequences that may encode a full-length protein includes

those sequences that are divergent by virtue of being degenerate in sequence. Further, one skilled in the art would recognize that, just as there exists degeneracy of the DNA code, there similarly exists amino acid substitutions that can be made to a polypeptide, which are conservative in nature, and which do not alter the basic properties of the residue that is replaced. The specification discloses "conservative amino acid substitutions." *See* U.S. 2004-0220092, at paragraphs **[0058]-[0059]**.

For these reasons, one skilled in the art would recognize that Applicants, at the time of filing, were in possession of SEQ ID NO:1 and SEQ ID NO:7, as well as sequences ***related*** to SEQ ID NO:1 and SEQ ID NO:7, in which the related sequences retain the recited functions. The rejection under 35 U.S.C. § 112, first paragraph for inadequate written description is requested to be reconsidered and withdrawn.

VIII. Rejection – 35 U.S.C. § 112, first paragraph, "Enablement"

Claims 19, 22, 26, and 28 were rejected under 35 U.S.C. § 112, first paragraph, allegedly "as failing to comply with the enablement requirement." In particular, claims 19, 22, and 26 were rejected allegedly for failing "to identify even a single assayable activity that has been attributed to that polypeptide." Applicants respectfully traverse the rejection for the following reasons.

As indicated above, SEQ ID NO:1 and SEQ ID NO:7 relate to cysteinyl leukotriene receptors. Assays for determining the activity of cysteinyl leukotriene receptors were well known in the art at the time the present application was filed. *See, e.g,* Heise, at EXPERIMENTAL PROCEDURES. Therefore, one skilled in the art would not have to engage in undue experimentation to practice the methods recited in claims 19, 22, and 26. Claim 28 has been cancelled. For the foregoing reasons, the rejection under 35 U.S.C. § 112, first paragraph for lack of enablement is requested to be reconsidered and withdrawn.

IX. Rejection – 35 U.S.C. § 112, second paragraph, "Indefiniteness"

Claims 3-7, 9, 13, 15-17, 19, 22, 26, and 28 were rejected under 35 U.S.C. § 112, second paragraph, allegedly "as being indefinite for failing to particular point out and distinctly claim the subject matter which applicant regards as the invention." In particular, the claims were alleged to be vague and indefinite because they lacked antecedent basis for one or more recited limitations. The claims have been amended accordingly. As such, reconsideration and withdrawal of this rejection is requested.

X. Rejection – 35 U.S.C. § 102, "Takasaki et al."

Claims 1-7, 9, 11, 13, 15-17, 19, 22 and 26 were rejected under 35 U.S.C. § 102(a) allegedly "as being clearly anticipated by the Takasaki et al. publication (B.B.R.C. 274(2):316-322, 02 Aug. 2000)" [hereinafter Takasaki]. Although Takasaki has an effective date for prior art purposes that is later than the claimed priority dates of the present application, the Examiner asserted that the present application and the priority application U.S. provisional application no. 60/193,051 do not meet the requirements of 35 U.S.C. § 112, first paragraph. As such, the Examiner concluded that the present application is not entitled to a priority date under 35 U.S.C. § 119(e) as of the filing date of provisional application no. 60/193,051. Applicants respectfully traverse the rejection for the following reasons.

In addition to provisional application no. 60/193,051, the present application claims the benefit of other U.S. provisional applications, including provisional application no. 60/199,084, filed on April 20, 2000, [hereinafter "the '084 application"], EXHIBIT 3. The '084 application includes substantially similar disclosure as the present application with respect to the pending claims. For example, the '084 application discloses SEQ ID NO:1 and SEQ ID NO:7 as SEQ ID NO:1 and SEQ ID NO:3, respectively. In addition, the '084 application asserts that SEQ ID NO:1 is a cysteinyl leukotriene receptor. *See* the '084 application, at TABLE 2. As noted above, Applicants respectfully contend that the present application fully complies with the requirements under 35 U.S.C. § 112 with respect to the pending claims. Therefore, for the same reasons that the present application complies with the requirements under 35 U.S.C. § 112 with respect to the pending claims, the '084

application complies the requirements under 35 U.S.C. § 112 with respect to the pending claims.

For these reasons, Applicants assert that the pending claims are entitled to a priority date at least as of the filing date of the '084 application (*i.e.*, April 20, 2004), which is earlier than the effective date of the Takasaki reference. As such, reconsideration and withdrawal of the rejection is requested.

XI. Conclusion

The present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. § 1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date 7/13/05

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